Nevada State Board of Pharmacy
431 W. Plumb Lane Reno, Nevada 89521
(775) 850-1440 (800)-364-2081 Fax (775) 850-1444
Institutional Inspection Form

: Nevada State Board of Pharmacy Inspector

SUBJECT: Self-Assessment Inspection Process

The Board of Pharmacy's established self-assessment inspection process provides management opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services. An inspection evaluation form must be obtained from the website to self assess compliance with Nevada pharmacy law. An inspector will review the form with you and inspect your facility during ***the month listed on your Inspection Notice***.

The procedure involves the following:

1. At the ***minimum***, print and fill out the self-assessment inspection form found on the website under your designated license type. We cannot evaluate or help you if we don't know what you don't know. Retain the form and have it **readily available** in a packet so **if you are not present** when an inspector arrives, your staff can have it available.

2. An inspector will conduct a review of your operation. Observations, along with your findings, will assure understanding and compliance with Nevada law.

Failure to fill out the inspection report suggests either you are not concerned with knowing the law or complying with it.

This plan has been established as a cooperative approach to annual inspections. We would appreciate any input you may have on this joint review procedure.

MANAGEMENT POLICIES, PROCEDURES AND SYSTEMS [NAC 639.468] (the inspection notice cover letter must be attached to this completed form) (circle yes compliant and no for not compliant. You may make comments as needed)

Has the managing pharmacist established policies, procedures and systems? Yes No

POLICY AND PROCEDURE MAINTENANCE [NAC 639.477]

Has the institution developed and carried out written policies and procedures regarding the distribution of drugs?
Date of Last Policy Review _____ Yes NA
Is the pharmacy open 24 hrs per day? Yes No
(If NO- has a specific policy been developed for handling drug orders when pharmacist off duty?) Yes NA
Does this policy include the following? (where applicable)
Access to pharmacy Yes NA
Access to drug room Yes NA
Access to night medication cart Yes NA
Access to operating room floor stock Yes NA
Is there a system to assign responsibility for the control and distribution of drugs? Yes NA
Persons authorized to access any of the drug storage areas listed above: (A typed/computer listing may be attached in lieu of listing personnel delegated such authority)

Name		

Is pharmacist "on-call" service available? Yes NA

RECORDS [21 CFR 1304 Records and Reports, NAC 639.482-490, NRS 453.246]

Are the following records maintained properly and for a period of 2 years?
[21 CFR 1304.04(a), NAC 639.482] Yes No
US Official Order Form-Schedule II
(DEA Form 222) [21 CFR Part 1305, NAC 639.487, NRS 453.251] Yes No
Security of un-negotiated forms Yes No
Forms properly executed? [21 CFR 1305.12] Yes No
Does the facility participate in the Controlled Substance Ordering System (CSOS)?
[21CFR1305.21-29] Yes No
Invoices of controlled substances: [21 CFR 1304.04(f)] Yes No
Schedule II invoices filed separately?
[21 CFR 1304.04(f)(1), NAC 639.489 (1)] Yes No

Schedule III-V invoices filed separately? [21 CFR 1304.04(f)(2), NAC 639.489 (2)]	Yes	No
Maintained at a central records location off site of the facility authorized by the DEA? [21 CFR 1304.04(a)(1), NAC 639.490]	Yes	No
Supplier Credit Memos of all controlled substances and dangerous drug returns? [NAC 639.487]	Yes	No
		No
Biennial inventory completed? [21 CFR 1304.11(c), NAC 639.487]	Yes	No
Date completed: _____	No	
Perpetual inventory of schedule II drugs? [NAC 639.485]	Yes	No
Has a new managing pharmacist started SINCE LAST INSPECTION? [NAC 453.475]	Yes	No
Start date: _____	No	
Was a controlled substance inventory completed for change of managing pharmacist	Yes	No
Date completed: _____		
Registrants inventory of Drugs Surrendered (drug destruction) [21 CFR 1307.21.NAC 639.487]	Yes	No
Are proper procedures for drug destruction followed? [NAC 639.050]	Yes	No
Has there been any loss of controlled substances SINCE LAST INSPECTION? (IF YES)	Yes	No
Report of Theft/Loss of Controlled Substances completed and submitted? [21 CFR 1301.76(B), NRS 453.568, NAC 639.487]	Yes	No
Were all losses reported within 10 days?	Yes	No
Reported to the DEA/Board of Pharmacy/Dept. of Public Safety?	Yes	No
Records of controlled substances from floor stock [NAC 639.486]	Yes	No
Recorded separate from patient record?	Yes	No
Record maintained by:<circle> Handwritten Electronic	Yes	No
If electronic, (system supplier?) _____		
Does the record contain?		
Name of patient	Yes	No
Name/dosage form/strength of controlled substance	Yes	No
Date/time administered	Yes	No
Quantity administered	Yes	No
Signature of person administering	Yes	No
Controlled substances returned to pharmacy	Yes	No
Record of waste/co-signed by another person	Yes	No
Records filed separate from patient records	Yes	No
DOES THE FACILITY HAVE AN ER/OR? (if NO skip down)	Yes	No
Does the facility allow for non-automated dispensing in the ER/OR?	Yes	No
Is a quality assurance process used to monitor compliance with the procedures and accountability for the controlled substances in the ER and OR?	Yes	No

Does the pharmacy distribute controlled substances to other facilities/practitioners? Yes No
(If YES provide records of controlled substances distributed to another pharmacy/practitioner) [NAC 639.488]
Invoices for schedule III-V: Yes No
- Date of distribution? Yes No
- Name/strength/quantity of controlled substances distributed? Yes No
- Distributing pharmacy's name, address and DEA number? Yes No
- Ordering party's name/address/DEA number? Yes No

Distribution of Schedule II controlled substances: No
- Does the institutional pharmacy retain copy 1, DEA Order Form DEA 222? Yes No
- Does it show the actual date of distribution? Yes No
- Does it show the quantity of controlled substances distributed? Yes No

STANDARDS FOR PREMISES [NAC 639.469]

Pharmacy facility [NAC 639.469]
Is space adequate for storage, compounding, labeling, dispensing, distribution and sterile preparation? (as applicable) Yes No
Is the space clean and well organized? Yes No
Is the space well lit and ventilated? Yes No
Is the sink clean and equipped with hot/cold water? Yes No
Is the temperature compatible for proper storage of drugs? Yes No
Locked storage area for schedule II controlled substances provided? Yes No
Can the pharmacy be secured to prevent theft/diversion of prescription drugs? Yes No
Is the pharmacy complying with local/state fire codes on storage of flammable materials in the pharmacy? Yes No
Pharmacy hours [NAC 639.479 NAC 630.480 and NAC 639.481]
Monday thru Friday _____
Saturday _____
Sunday _____
Holidays _____
Security [NAC 639.470]
Are all areas able to be locked to prevent unauthorized access (pharmacy, carts, etc.)? Yes No
Is there a system of key control? Yes No

Equipment [NAC 639.471]
If non-sterile compounding is done at your facility, print and complete Non-Sterile Compounding addendum.

Mechanical devices NAC 639.715 NAC 639.718 NAC 639.720 NAC 639.725

Are all prescription pharmaceuticals checked for accuracy by a pharmacist and documented by the pharmacist as approved for use in the mechanical device prior to placing the pharmaceuticals in the device (example Pyxis, Yuyuma)?	Yes	No
Are the records kept readily available for review for a minimum of 2 years?	Yes	No
Refrigeration?	Yes	No
Temperature appropriate to drug stored?	Yes	No
Sanitation acceptable?	Yes	No
If compounding:		No
Scales?	Yes	No
Electronic?	Yes	No
Traditional?	Yes	No
Weights? (if traditional scale)	Yes	No
Mortar and pestle?	Yes	No
Appropriate graduates, molds, presses?	Yes	No
Reference Library [NAC 639.472]		
Current state statues/regulations relating to pharmacy?	Yes	No
Current references relating to practice available?		
<circle> Written Electronic	Yes	No

SPECIFICATION, PROCUREMENT AND STORAGE OF DRUGS [NAC 639.473]

Outdated/mislabeled or adulterated drugs in stock available for dispensing?	Yes	No
Is outdated stock maintained separately?	Yes	No
How is outdated stock disposed of? _____	Yes	No
External/internal medications separated on the nursing units?	Yes	No
Does this pharmacy prepackage drugs? [NAC 639.476]		
(if NO skip to next section)	Yes	No
Is labeling correct?	Yes	No
Are records maintained for 2 years?	Yes	No
Are records complete per the following list?	Yes	No
Name/strength/dosage form of drug	Yes	No
Pharmacy's lot number	Yes	No
Name of manufacturer	Yes	No
Manufacturer's lot number	Yes	No
Manufacturer's expiration date on drug	Yes	No
Quantity per package	Yes	No
The number of packages	Yes	No
Date it was packaged and assigned expiration date	Yes	No
Initials of pharmacist	Yes	No

DISTRIBUTION OF DRUGS

Limitations on distribution of drugs [NAC 639.478]

Only upon order of a practitioner or his agent?	Yes	No
Original/direct copy of practitioner's order?	Yes	No
Does a written policy regarding automatic stop orders exist?	Yes	No

NON 24 HOUR PHARMACIES ONLY:

Withdrawal of drug by non-pharmacist [NRS 639.2324, NAC 639.479, NAC 639.480,NAC 639.481]

Quality limited to immediate medical needs?	Yes	No
Designated licensed nurse/practitioner removed the product?	Yes	No
Proper record maintained?	Yes	No
Practitioner's order forwarded to pharmacy?	Yes	No
Pharmacist reconciled balance within 7 days?	Yes	No
Name of Patient?	Yes	No
Name, strength and quantity of drug?	Yes	No
Directions for use? [NRS 639.2353 3., NRS 454.223, NAC 453.015]	Yes	No
The date of issue?	Yes	No

PARENTERAL PREPARATIONS [NAC 639.674-NAC 639.692] [LCB file R035-06]

Does the facility provide parenteral preparation services**?**	Yes	No

Does the pharmacy prepare cytotoxic agents/hazardous drugs (carcinogenicity/teratogenicity or other development toxicity/reproductive toxicity/organ toxicity at low doses/genotoicity/compounded drug product) whose structure and/or toxicity profiles mimics an existing drug product that produces one or more of the characters noted?	Yes	No

Fill out the Nevada State Board of Pharmacy Institutional/Parenteral Inspection form addendum if you answered yes to either of the above 2 questions.

INVESTIGATIONAL DRUGS [NAC 639.455, NAC 477(b) and NAC 639.468, 13.]

Does the pharmacy have an investigational drug system? (if NO skip to P&T)	Yes	NA
Are policies and procedures in place?	Yes	NA
Drug protocol on file in pharmacy?	Yes	NA
Approved by Pharmacy and Therapeutics Committee? Date:_____	Yes	NA
Dispensing controlled by pharmacy?	Yes	NA

PHARMACY AND THERAPEUTICS COMMITTEE [NAC 639.453, NAC 639.464, NAC 639.468]

Pharmacist a voting member?	Yes	No
Has a Hospital Formulary been developed? [NAC 639.474]	Yes	No
• Is it available to patient care areas?	Yes	No
• Is it available to patients?	Yes	No
Formulary/drug list prepared and updated by committee? [NAC 639.474]	Yes	No
Date of last meeting? _____		No
Written medication management policies been approved by the committee?	Yes	No
Does managing pharmacist determine drug specifications?	Yes	No

GENERAL:

Are equivalency charts and standard abbreviations posted on nursing units?	Yes	No
Is the telephone number of a poison control center posted in the pharmacy and in the nursing units? [NAC 639.468,8(b)]	Yes	No
Do licensed personnel wear identification badges?	Yes	No
Are controlled substance registration certificates posted?	Yes	No
Are monthly reports of inspections of nursing units and drug storage areas by the department Pharmacy available?	Yes	No

Sterile Compounding

(note: pages 1-7 are for institutional inspections only and will missing for non-institutional inspections.)

For each standard,

- ***Mark "X" in the compliant box if your facility is 100% compliant with that standard.***
- ***If facility never compounds under a specific requirement mark "X" in the N/A box or note NA by the section header.***
- ***If you are compliant with an item, but not in the exact manner stated due to an exception described below, please place the letters "EX" for "Exception" in the compliant box.***
- ***If non-compliant, provide an explanation and action plan for correction.***
- ***If an exception, provide documentation of equivalence or superiority.***
- ***Have all environmental, training, competencies, exceptions, action plans, and all other related documents available for review.***
  USP <797> states, "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."
- ***Note: The included references to NAC are a guide. Additional regulations and/or statutes may apply. It is your responsibility to understand and comply with all administrative codes and statutes related to the compounding you intend to do.***

Standard Operating Procedures NAC 639.67015

The licensed pharmacy listed above shall have a written Standard Operating Procedures Manual (SOP) (or Policy and Procedure Manual) with detailed instructions that describe how, when (frequency), and by whom all requirements in LCB file R035-06 (Legislative Counsel Bureau) and all other relevant Nevada Revised Statues (NRS) and Administrative Codes (NAC) are to be met.

Personnel Training and Evaluation Documentation NAC 639.67013, 639.67053

Attach a list certifying the personnel on the list are competent and proficient to correctly perform all the tasks related to the sterile risk level (note risk level by their name) they are compounding at. Please sign, print your name and date the list. (Please refer to the remarks page for instructions on the certification list.)-NAC 639.67013

Documentation is on file, for EACH person who compounds sterile and/or non-sterile products, that the person is competent and proficient to correctly perform all tasks related to sterile and/or non-sterile compounding and has received on an ongoing basis sufficient training to maintain that competency and proficiency. The didactic training and/or observational documentation includes, but is not limited to:	Yes	No
All compounded prescriptions are only prepared to fill: (a) a patient specific prescription, (b) a chart order for immediate use by the patient, or (c) to prepare for the filling of future patient specific prescriptions or chart orders based upon the previous use of the history of a practitioner and patient who regularly uses the pharmacy.	Yes	No
The compounded drug is only sold to the patient, the agent of the patient, or a practitioner who will be administering the drug(s) to the patient. The compounded product must be dispensed or sent directly to the patient. (non-institutional sterile compounders)	Yes	No
Compounded products are always dispensed pursuant to a prescription or chart order and are never dispensed pursuant to an invoice or other request for sale from a practitioner.	Yes	No
Records for employees on hire or newly assigned to compound drugs products at a higher risk level and on an ongoing basis:		
• Perform aseptic hand cleansing	Yes	No
• Perform disinfection of compounding surfaces	Yes	No
• Select and appropriately don protective garb	Yes	No
• Competency in calculations, Identifying, weighing and measuring ingredients	Yes	No
• Procedures for containment, cleaning and disposal with regard to breaks and spills	Yes	No
• Appropriate documentation of training of any non pharmacy personnel cleaning and/or disinfecting or entering ISO areas	Yes	No

Additional Training for Hazardous Drugs, if applicable, including but not limited to NAC 639.67079**:**		
○ **Protection of personnel and compounding environment from contamination by hazardous drugs**	Yes	No
○ Treatment of employees of the pharmacy with regard to contact and inhalation exposure	Yes	No
○ Negative pressure techniques	Yes	No
○ Containment, cleanup and disposal procedures	Yes	No
Radiopharmaceuticals Training, if applicable, including but not limited to:		
○ Compounding, handling, cleaning and special techniques	Yes	NA
○ Certification of and display of pharmacists certificate in nuclear pharmacy	Yes	NA
Media Fill testing NAC 639.6649		
• Appropriate to risk level (Manipulate sterile products aseptically)	Yes	No
• Minimum of every 12 months for low or medium risk compounding, or 6 months if compounding high risk products	Yes	No
Glove Fingertip Sampling NAC 639.6633		
○ Minimum of every 12 months for low or medium risk compounding or 6 months if compounding high risk products	Yes	No
○ Sampled immediately after hand hygiene and garbing for both hands including a thumb sample from each hand	Yes	No
○ Action Level: ISO 5 >0 colony forming units (CFU)	Yes	No
○ Report CFU total is for both gloves – CFU count is documented per hand	Yes	No

Environmental Cleaning, and Equipment Documentation NAC 639.6705

Certifications for all Primary Engineering Controls (referred to as PECs in this document) (attach a copy of each certification) <u>The PEC and Secondary Engineering control information must be filled out. . (Testing shall be performed in a dynamic work environment - CAG-003-2006 revised December 8, 2008 CETA certification guide for sterile compounding facilities)</u>

Additional certification from the manufacturer for any PEC that maintains ISO Class 5 environment in the general non-controlled environment). (attach a copy of each certification)

(Laminar Flow Bench Horizontal or Vertical/ Biological Safety Cabinet (Isolator/Barrier)/ Compounding Aseptic Isolator/Compounding Aseptic Containment Isolator /Clean Room (ISO 5)/ Identify any other type of PEC used.

Enter type of PEC(s) and attach certification & highest risk level it is used for	Model #	Cert. Date	Comments/PEC location (if multiple PECs)

Secondary Engineering controls	ISO class certification		
Buffer area (ISO 7 or better)			
Buffer area (ISO 7 or better)			
Buffer area (ISO 7 or better)			
Ante area (ISO 8 or better)			
Ante area (ISO 8 or better)			
Ante area (ISO 8 or better)			

Room Pressurization Test Results certification of ISO CLASS 7 BUFFER AREA and ISO CLASS 8 ANTE AREA (both every 6 months) ***0.02-0.05 inch water column pressure differential between areas***		
Pressure gauges or velocity meters are installed to monitor pressure differential or air flow between the buffer area and the ante area and the general environment outside the compounding area. (if applicable)	Yes	NA
• *Positive Pressure Gauge daily log (ISO CLASS 7 BUFFER AREA and ISO CLASS 8 ANTE AREA) (Circle if* ***ELECTRONICALLY RECORDED****)* ***(minimum of daily if manual) (UPS 797)***	Yes	NA
• *Negative Pressure Gauge daily log (ISO CLASS 7 BUFFER AREA and ISO CLASS 8 ANTE AREA) (Circle if* ***ELECTRONICALLY RECORDED****)* ***(minimum of daily if manual) (USP797)***	Yes	NA
Air Quality Testing of ISO Class 5, ISO CLASS 7 BUFFER AREA and ISO CLASS 8 BUFFER AREA environment certification		
Viable and Non-Viable Air Particle Sampling NAC 639.67051		
• Non-Viable Particle Sampling **(attach a copy of each certification) (every 6 months)**	Yes	No
• Viable Particle Sampling **(periodic sampling in conjunction with observational aseptic technique)**	Yes	No
• Microbial Air Sampling – Volumetric or other		
○ Recommended action Levels (CFUs per cubic meter/1000 liters) of air per plate: ISO 5 >1 ISO 7 >10 ISO 8 >100 (corrective action dictated by identification of microorganisms recovered)		
• Microbial Surface Sampling	Yes	No
○ Recommended action Levels: ISO 5 >3 ISO 7 >5 ISO 8 >100 (corrective action dictated by identification of microorganisms recovered)		
• Records of any remedial actions taken to return to environment to correct ISO class	Yes	No
Clean Room temperature and humidity log *(Circle if* ***ELECTRONICALLY RECORDED*****)**	Yes	No
Refrigerator and Freezer Logs *(Circle if* ***ELECTRONICALLY RECORDED)***	Yes	No
Cleaning/Sanitation Documentation log	NA	No
PEC requirements		
• Daily requirements		
○ At beginning of each shift, before each batch, no longer than 30 minutes following previous disinfection when ongoing compounding activities are occurring, after spills and when surface contamination is known or suspected	Yes	No
○ Counter and easily cleanable work surfaces	Yes	No

○ Floors	Yes	No
• Monthly requirements	Yes	No
○ Walls, Ceilings, Storage Shelving	Yes	No
• Records of any spill or suspected contamination and corrective action taken	Yes	No
High Risk Compounding Sterilization log		
• Sterilization records including, but not limited to:		
○ Sterilization failures and corrective action taken	Yes	NA
○ Integrity testing, including, without limitation, the bubble point test, according to manufacturer's recommendations	Yes	NA
○ Bacterial endotoxin testing results	Yes	NA
Hazardous Drug Waste Disposal log		
• P category drugs - (acutely hazardous) - examples warfarin, epinephrine	Yes	NA
• U category drugs – examples include chemotherapeutic drugs	Yes	NA
• D category drugs – exhibit ignitability, corrosivity, reactivity, or toxicity	Yes	NA
Compounding Records NAC 639.67019		
• Maintain for 2 years	Yes	No
EXCEPTION: The record of all sterile compounded drugs products compounded by a pharmacy (other than an institutional pharmacy) and for all sterile products for parenteral nutrition and sterile anti-neoplastic drug products compounded by an institutional pharmacy must be maintained for 6 months		
• All compounding/batch records contain the following but are not limited to:	Yes	No
○ All necessary compounding instructions.		
○ A complete list of sterilizing parameters, if sterilization is necessary.		
○ The equipment used in the compounding/sterilization.		
○ Reconciliation and yield of the batch.		
○ All equipment such as beakers and glassware are clearly marked with the product name and lot# during the compounding process.		
○ Record of sterilization of components used including by limited to rubber caps, vials and product.		
○ Sign off by compounding personnel and the pharmacist approving the batch.		
○ Documentation of all testing, including but not limited to, sterility, endodotoxin and concentration is attached to the compounding record or is cross referenced to the record of testing results.		
• Are beyond use dates used that exceed those identified in Nevada Administrative code?	Yes	No
○ The beyond use date is only used if the batch is compounded exactly as directed by the master compounding record.	Yes	No
○ Documentation is available on site to support the extended beyond use date.	Yes	No
• A log/record is maintained, in addition to the batch record. The record shall document, but is not limited to, any sub or super potent lots, endotoxin, sterility, or other problems with the batch and documents the disposition of each batch.	Yes	No

Equipment Records		
• Records are available for review for all equipment used in compounding. The records include but are not limited to equipment setup, calibration, filter changes, equipment failures and repair, any periodic testing required and cleaning of equipment. (attach a copy of all required certifications/testing)	Yes	No
• Records of all equipment calibrations, routine maintenance and periodic testing (according to the manufacturer's recommendations) are kept for the life of the equipment (USP 797)	Yes	No
Automated Compounding Devices log NAC 639.67017		
• Cleaning/Calibration/Maintenance Log	Yes	No
• All training and environmental records must be readily available for review for the last 2 years.	Yes	No
Autoclaves / Dry Ovens /Incubators		
• Is biological indicator or other testing required, according to the manufacturer's literature, to validate the efficiency of the autoclave(s) being done and documented?	Yes	NA
Scales/Balances	Yes	No
Other equipment (attach list)	Yes	No
CSP Microbial Contamination Risk Levels		
Low risk Level CSPs NAC 639.67061 NAC 639.67063		
Compounding involves only transfer, measuring and mixing manipulations using not more than 3 commercially manufactured sterile products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product	Yes	No
Manipulations are limited to aseptically opening ampoules, penetrating disinfected stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing	Yes	No
In the absence of sterility tests, storage is not more than 48 hours at 20-25 degrees C (68-77 F), 14 days at cold temperature 2-8 degrees C (36-46 F), and 45 days in a solid frozen state of -10 degrees (14 F) or colder	Yes	No
Medium Risk Level CSPs NAC 639.67065		
Aseptic manipulations within an ISO Class 5 environment of unusually long duration or complex aseptic manipulation , with more than 3 sterile products or other entries into one container, including, without limitation, a bag or vial, to make the final compounded drug product	Yes	NA
The final CSP is treated as medium risk if the CSP does not contain broad-spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours	Yes	NA
In the absence of sterility tests, storage is not more than 30 hours at controlled room temperature 20-25 degrees C, 9 days at cold temperature 2-8 degrees C, and 45 days in a frozen state of to -10 C or colder	Yes	NA

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STERILE COMPOUNDING NAC 639.66611-639.67079 (LCB FILE R035-06) ADDENDUM

High Risk Level CSPs NAC 639.67067, 639.67069, 639.67071		
Sterilization methods are verified to achieve sterility for the quantity and type of containers	Yes	NA
Sterilization methods are chosen based on appropriate method for the pharmaceutical product being sterilized	Yes	NA
High risk sterile compounded drugs for injection into the vascular system or central nervous system or high risk sterile compounded drugs for inhalation or ophthalmic use must perform sterility tests for:		
○ CSPs if they are prepared in batches > 25 individual single dose packages	Yes	NA
○ Compounded in multiple-dose vials for administration to multiple patients	Yes	NA
○ Will be exposed for a period of more than:		
▪ 12 hours in temperatures 2-8 degrees C	Yes	NA
▪ 6 hours in temperatures exceeding 8 degrees C	Yes	NA
Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high risk sterile compounded product must not exceed: 24 hours at controlled room temperature 20-25 degrees C, 3 days at cold temperature 2-8 degrees C, and 45 days in a solid frozen state of -10 C or colder. (NAC 639.67067 sub 2.)	Yes	NA
• If assigning a beyond use longer than allowed under NAC, all formulas, even those containing the same ingredients but different concentrations, must have documentation supporting the extended dating for both sterility and potency.		
• NAC beyond use dates must be used if there is any variation from any formula or variation in the compounding process.		
High Risk Nonsterile Ingredients and Devices used to make CSP's (USP 797)		
Date of receipt of bulk product is noted on the container	Yes	NA
Packages of ingredients that lack a supplier expiration date are assigned an expiration date not to exceed 1 year based on the nature of the component and it's degradation mechanism, the container in which it is packaged and the storage conditions Appropriate inspection and testing should be done to ensue the ingredient has retained purity and quality. Have documentation available. (USP 797)		
If a product is transferred from the original manufacturer's container, the container is identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container	Yes	NA
Compounded product's active ingredients must meet one of the following three standards:		
Non sterile ingredients, substances and excipients are official USP or NF grade. All Certificates of Analysis (COA) are on file.	Yes	NA
If non USP or NF food, cosmetics or other substances are used, the active ingredients are from an approved FDA manufacturer or distributor and are accompanied by a Certificates of Analysis. All Certificates are on file.	Yes	NA
If neither 1 nor 2 are met, the active ingredients have been certified by the compounding pharmacy through independent analysis by a laboratory to the satisfaction of the Board.	Yes	NA

Circle sources of non USP or NF substances:	Other (list):
Analytical Reagent (ARA):	
Certified American Chemical Society (ACS):	
Food Chemicals Codex grade (FCC):	

Unless the person who prepares the CSP immediately witnesses or completely administers it, the CSP is labeled with patient identifier, names and amounts of all ingredients, initials of the compounder, and the exact 1-hour BUD and time		
Immediate Use CSPs NAC 639.67073, 639.67075		
If administration has not begun within 1 hour of being compounded, CSP is discarded unless a period longer than one hour is required for compounding	Yes	No
Administration begins not later than 1 hour following the start of the preparation of the CSP and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the drug product began or the CSP is disposed of promptly and safely	Yes	No
Aseptic technique is followed and if not immediately administered, CSP is continually supervised	Yes	No
Unless the person who prepares the CSP immediately witnesses or completely administers the CSP, the CSP is labeled with the patient identifier, names and amounts of all ingredients, initials of the compounder and the exact 1 hour BUD and time.	Yes	No
No more than six sterile non-hazardous commercial drug products are used, excluding infusion solutions or diluents.	Yes	No
Single Dose and Multiple Dose Containers NAC 639.67057		
In the course of compounding a drug product a single-dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product seal is breached, the time and date of the breach is marked on the container	Yes	No
• Single-dose containers entered in worse than ISO Class 5 air quality and stored in worse than ISO 7 are used within 1 hour of entry	Yes	No
• Single-dose containers entered in ISO Class 5 or cleaner air and are stored in ISO 7 or cleaner are used within 6 hours of entry	Yes	No
• Single-dose containers entered in ISO 5 or cleaner air quality and remains in ISO 5 air quality are used within 24 hours	Yes	No
Opened single-dose ampoules are not stored. If the entire seal has been removed for a multi-use vial the contents are not stored	Yes	No
Closure sealed multiple-dose containers are used within 28 days after initial opening or entry	Yes	No
Hazardous Drugs as CSPs NAC 639.67077, 639.67079		
Hazardous drugs are stored separately from other inventory	Yes	No
Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal	Yes	No
Hazardous drugs are prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas	Yes	No
Disposal of hazardous waste complies with all applicable federal, state and local regulations	Yes	No
If one of the components of a hazardous drugs is an anti-neoplastic drug, radiopharmaceutical drug, or a drug whose manufacture has recommended that the drug only be compounded in an ISO 5 environment in either a biological safety cabinet (BSC) or a compounding aseptic containment isolator(CACI)		

• CSP is prepared in a BSC or a CACI that meets or exceeds standards	Yes	No
• BSC or CACI is vented outside the building if one or more components of the compounded hazardous drug is an anti-neoplastic drug	Yes	No
Access is limited to areas where hazardous drugs are stored and prepared	Yes	No
Personnel who compound hazardous drugs are trained in storage, handling, compounding, safety procedures and disposal of drugs prior to preparing or handling hazardous CSPs	No	No
Radiopharmaceuticals as CSPs NAC 639.67063		
Radiopharmaceuticals are compounded using appropriately shielded vials and syringes in a properly functioning and certified vertical laminar airflow hood or CLASS II type B2 biological safety cabinet that is located in an environment with an air quality of ISO Class 8 or higher.	Yes	NA
Only shielded vials, syringes and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process	Yes	NA
Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a molybdenum-Technetium-99m generator systems are stored and operated under conditions recommended by manufacturers and applicable state and federal regulations; such xgenerator systems are operated in an ISO Class 8 or cleaner air environment	Yes	NA
Materials and garb exposed in patient care and treatment do not cross the line of demarcation (USP)	Yes	NA
Low Risk – The final compounded drug product contains a volume of 15 milliliters or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a molybdenum—99m generator; or the final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives and which have expiration times of 72 hours or less	Yes	NA
NAC 639.5802-639.584 Radiopharmaceuticals as CSPs (Nuclear Pharmacies) NAC 639.67063		
The pharmacy meets space requirements (NAC 639.5822)	Yes	NA
• A nuclear pharmacy must have adequate space and equipment commensurate with the scope of services it provides and must meet the minimum space requirements established for all pharmacies in the State.	Yes	NA
A nuclear pharmacy must include, but is not limited to, an area for the:	Yes	NA
• Preparation and dispensation of radiopharmaceuticals	Yes	NA
• Shipment and receipt of radioactive material	Yes	NA
• Storage of radioactive material	Yes	NA
• Decay of radioactive waste	Yes	NA
The pharmacy must have, but is not limited to, the following equipment		
• A radionuclide dose calibrator	Yes	NA
• A refrigerator	Yes	NA
• A single or multiple channel well scintillation counter containing the isotopes sodium iodide, thallium, germanium and lithium	Yes	NA
• A radiochemical fume hood and filter system with suitable equipment for sampling air	Yes	NA
• An area survey meter	Yes	NA

• At least two Geiger Mueller survey meters, including one high-range meter	Yes	NA
• A microscope and hemacytometer	Yes	NA
• A laminar airflow hood and appropriate supplies to ensure sterile practices for parenteral solutions	Yes	NA
• Radiation shields for syringes and vials	Yes	NA
• A lead-shielded drawing station	Yes	NA
• Decontamination supplies	Yes	NA
• Appropriate supplies to perform procedures to assure the quality of radiopharmaceuticals	Yes	NA
• Lead transport shields for syringes and vials	Yes	NA
• USA Type A, 7A transport containers approved by the Department of Transportation and other labels and supplies for shipping radioactive materials	Yes	NA
Environmental Quality Control		
Facility Design and Environmental Controls		
Maintain records of any equipment or other mechanical non-compliance, and a record of corrections or retesting done. Records of equipment or mechanical failure shows the time frame the system was non-compliant and the methodology or backup processes the facility used to maintain compliance	Yes	No
Compounding facility provides an appropriate temperature and well-lighted working environment	Yes	No
Policies and procedures for PEC area are written and followed; determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs	Yes	No
Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are non-permeable, non-shedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected	Yes	No
The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and non-shedding; the surfaces are resistant to damage by disinfectant agents	Yes	No
Junctures of ceilings to walls are coved or caulked	Yes	No
If ceilings consist of inlaid panels, the panels are impregnated with a polymer to render them impervious and hydrophobic; they are caulked around each perimeter	Yes	No
The exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush and sealed; any other penetrations through the ceiling or walls are sealed	Yes	No
The buffer area does not contain sources of water (sinks) or floor drains	Yes	No
Works surfaces are constructed of smooth, impervious materials	Yes	No
Carts are stainless steel wire, nonporous plastic or sheet metal with cleanable casters	Yes	No
Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection	Yes	No

Placement of Primary Engineering Controls		
PECs are located within a restricted access ISO Class 7 buffer area unless an exception is met	Yes	No
Designated areas are maintained in a clean condition and have cleanable surfaces, including walls, ceilings and floors	Yes	No
(If not run continuously) the recovery time to achieve ISO Class 5 air quality of PECs used for sterile compounding is documented, pharmacy personnel are aware of the recovery time necessary and internal procedures are developed to ensure the ISO 5 environment is reached and maintained	Yes	No
Media that supports the growth of fungi is used in high-risk level environments	Yes	No
NAC 639.472,NAC 639.475, NAC 639.672, NAC 639.674-639.690		
Designated work areas have cleanable surfaces including walls, ceilings and floors	Yes	No
Designed work areas are ventilated so as to not interfere with Laminar Flow Hood	Yes	No
There are no obstructions to the intake of the Laminar Flow Hood	Yes	No
Sufficient storage space is well separated from the area of the Laminar Flow Hood for storage of bulk materials equipment and waste materials	Yes	No
There is a sink with hot and cold running water in the pharmacy	Yes	No
Refrigerator and Freezer are of sufficient capacity to store all materials requiring refrigeration or freezer storage	Yes	No
Reference Materials must include but are not limited to :	Yes	No
• Drugs and chemicals used in services related to parenteral therapy	Yes	No
• Parenteral therapy activities, including manufacturing, dispensing, distribution and counseling	Yes	No
• Compatibility information	Yes	No
• Policy and Procedures on, but not limited to:	Yes	No
○ Drug recalls	Yes	No
○ Cleaning and sanitation	Yes	No
○ Justification of beyond use date on compounded solutions	Yes	No
○ Methods used to provide parenteral therapy services	Yes	No
○ Preparation and labeling of admixtures	Yes	No
○ Labeling, in addition to other requirements must include the following:	Yes	No
▪ The telephone number of the pharmacy (not required for inpatients)	Yes	No
▪ Name and concentrations of all ingredients in the parenteral solution	Yes	No
▪ Instructions for storage and handling	Yes	No
Additional Personnel Requirements		
A pharmacy or pharmacist engaged in the practice of compounding drug products may not allow any food or drink to be stored or consumed in or at an area or room in the pharmacy that is designated for compounding (sec. 26)	Yes	No
Cleaning and Disinfecting the Compounding Area		
When compounding activities require the manipulation of blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation and are controlled by specific SOPs to avoid any cross-contamination	Yes	NA

Personnel Cleansing and Garbing		
All cleaning materials are non-shedding and dedicated to use in the buffer or clean area, ante-area, and segregated areas and are not removed from these areas except for disposal	Yes	No
No shipping cartons are taken into the buffer area, clean area or segregated compounding area	Yes	No
Elements of Quality Control		
Quality assurance practices include routine disinfection and air quality testing, visual confirmation that personnel are appropriately garbed, review of all orders for correct identity and strength, visual inspection of CSPs	Yes	No
All devices used to compound a CSP operate properly within acceptable tolerance limits, as determined by the device'-s manufacturer or any regulations that govern the use of that device	Yes	No
For all equipment, SOPs exist and are followed that state routine maintenance required and frequency of calibration, annual maintenance, monitoring for proper function, and procedures for use	Yes	No
Results from equipment maintenance and calibration are kept for the lifetime of the equipment (USP 797)	Yes	No
Verification of Automatic Compounding Devices		
If compounding a product for parenteral nutrition, maximum limits are established and are entered for each additive into the computer or an audible alarm or other mechanism alerts the pharmacist that the maximum dose is has been exceeded. The automatic compounding device will cease compounding the drug product for parenteral nutrition if the maximum limit for an additive will be exceeded	Yes	NA
Finished Preparation Release Checks and Testing		
All CSPs are visually inspected for being intact with no abnormal particulate matter, and prescriptions and written compounding procedures are reviewed to verify accuracy of correct ingredients and amounts, aseptic mixing, high-risk sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed	Yes	No
A check system is in place that meets state regulations that includes label accuracy and accuracy of the addition of all ingredients used	Yes	No
High-risk level CSPs must be sterility tested if they are prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized	Yes	No
High-risk level CSPs must be pyrogen tested, excluding those for inhalation or ophthalmic administration, if prepared in batches of > 25 identical containers, or exposed longer than 12 hours at 2 to 8 degrees and 6 hours at warmer than 8 degrees before being sterilized	Yes	No
Maintaining Sterility Purity and Stability of Dispensed and Distributed CSPs		
The facilities have written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity and strength of CSPs	Yes	No
Chemotoxic and other hazardous CSPs have safeguards to maintain the integrity of the CSP and minimize the exposure potential of these products to the environment and personnel	Yes	No

Delivery and patient-care-setting personnel are properly trained to deliver the CSP to the appropriate storage location	Yes	No
Outdated and unused CSPs are returned to the compounding facility for disposition as appropriate	Yes	No
SOPs exist to ensure that the storage conditions in the patient-care setting are suitable for the CSP specific storage requirements	Yes	No

Provide a list certifying the personnel on the list are competent and proficient to correctly perform all the tasks related to sterile compounding. The list must identify all competencies including didactic, observational and manipulative training received. The list should include all elements listed under training for non-hazardous compounding for the risk level (identify the risk level) you are certifying the person to perform and a separate list for hazardous certification (if applicable). Please review the sterile compounding addendum for documentation and training elements that should be addressed at a minimum. Additional training should also be noted. (Refer to sections: records for employees on hire or newly assigned, additional training for hazardous drugs, radiopharmaceutical training, media fill training, glove fingertip sampling, automated compounding devices). Sign and date the list. Your signature on this document also certifies that all documents related to this certification are on file and available for review.

REMARKS:

If you are required to provide any documentation to the inspector via fax or email attach a copy of the document(s) to this inspection form for future review. If you are required to fax or email information, fax to 702-486-7903 for inspections completed by the Las Vegas Board office or 775-850-1444 for inspections completed by the Reno office. Clearly identify the facility on all documents.

If you are not an institutional pharmacy doing sterile and/or non-sterile compounding refer to the retail inspection form and the non-sterile addendum for additional remarks.

Nevada State Board of Pharmacy
431 W. Plumb Lane Reno, Nevada 89521
(775) 850-1440 (800)-364-2081 Fax (775) 850-1444
STERILE COMPOUNDING NAC 639.66611-639.67079 (LCB FILE R035-06) ADDENDUM

PRINT

SIGN

Managing/Consultant Pharmacist Date Board of Pharmacy Inspector Date

Your pharmacy has been inspected by an agent of the Nevada State Board of Pharmacy. Conditions that require remedial action are listed in the remarks section above and they must be corrected within the time frame(s) stated to ensure compliance with laws and regulations governing the practice of pharmacy. I acknowledge that the noted unsatisfactory conditions have been explained to me and that I have received a copy of this Inspection report.